

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078912817

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078912848



# MATERIAL SAFETY DATA SHEET

Revision date: 07-Dec-2010

Version: 2.0

Page 1 of 7

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica Bacterin-Toxoid**

Trade Name: One Shot Ultra 7  
Chemical Family: Mixture  
Intended Use: Veterinary Vaccine

## 2. HAZARDS IDENTIFICATION

Appearance: Freeze-dried preparation  
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Short Term: May cause eye and skin irritation. May cause allergic reaction. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

EU Indication of danger: Irritant

EU Hazard Symbols:

**Xi**



EU Risk Phrases:

Australian Hazard Classification (NOHSC):

R43 - May cause sensitization by skin contact.  
Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 2 of 7

Version: 2.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Saponin	8047-15-2	232-462-6	Not Listed	*
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	0.1 - <1.0%
Aluminum potassium sulfate	7784-24-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Clostridium perfringens type C	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium chauvoei	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium sordellii	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium septicum	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium perfringens type D	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium novyi	NOT ASSIGNED	Not Listed	Not Listed	*
Pasteurella haemolytica	NOT ASSIGNED	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	As for primary cause of fire.
<b>Hazardous Combustion Products:</b>	Not known
<b>Fire Fighting Procedures:</b>	Dike and collect water used to fight fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-  
sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 3 of 7

Version: 2.0

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

<b>General Handling:</b>	Use with adequate ventilation. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing.
<b>Storage Conditions:</b>	Store under refrigeration in closed container.
<b>Storage Temperature:</b>	2-7°C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Listed
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	0.3 ppm MAK
	0.37 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	0.5 ppm-Action Level
	0.75 ppm-TWA
	2 ppm-STEL

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 4 of 7

Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.
<b>Respiratory protection:</b>	In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Freeze-dried preparation	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable
<b>Conditions to Avoid:</b>	Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.

### 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content.
-----------------------------	--

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Formaldehyde

Rat Oral LD50 800 mg/kg

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 5 of 7

Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

**Skin Irritation / Sensitization** This product contains formaldehyde which is considered to be a skin sensitizer.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity

Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive

*In Vitro* Chromosome Aberration Rodent Positive

*In Vitro* Sister Chromatid Exchange Rodent Positive

*In Vivo* Chromosome Aberration Not specified Positive

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

#### Carcinogen Status:

Contains formaldehyde: potential cancer hazard. See below

##### Formaldehyde

**IARC:** Group 1

**NTP:** Listed

**OSHA:** Present

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

Releases to the environment should be avoided. The environmental characteristics of this material have not been fully evaluated.

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-  
sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 6 of 7

Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**EU Symbol:** Xi  
**EU Indication of danger:** Irritant

**EU Risk Phrases:**  
R43 - May cause sensitization by skin contact.

**EU Safety Phrases:**  
S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
WARNING  
May cause allergic skin reaction.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A

**Xi**



#### **Saponin**

**Australia (AICS):**  
**EU EINECS/ELINCS List**

Listed  
232-462-6

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-  
sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 7 of 7

Version: 2.0

### 15. REGULATORY INFORMATION

#### Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1% de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb TPQ
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen, initial date 1/1/88 (gas)
	0.5 ppm-Action Level
	0.75 ppm-TWA
	2 ppm-STEL
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

#### Aluminum potassium sulfate

Australia (AICS):	Listed
-------------------	--------

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R34 - Causes burns.  
R43 - May cause sensitization by skin contact.  
R40 - Limited evidence of a carcinogenic effect  
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**





# MATERIAL SAFETY DATA SHEET

Revision date: 07-Dec-2010

Version: 2.0

Page 1 of 7

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Animal Health  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017  
Poison Control Center Phone: 1-866-531-8896  
Technical Services Phone: 1-800-366-5288  
Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd,  
Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica Bacterin-Toxoid**

Trade Name: One Shot Ultra 7  
Chemical Family: Mixture  
Intended Use: Veterinary Vaccine

## 2. HAZARDS IDENTIFICATION

Appearance: Freeze-dried preparation  
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Short Term: May cause eye and skin irritation. May cause allergic reaction. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Saponins have little toxicity for humans when ingested but have hemolytic effects when injected intravenously.

EU Indication of danger: Irritant

EU Hazard Symbols:

**Xi**



EU Risk Phrases:

Australian Hazard Classification (NOHSC): R43 - May cause sensitization by skin contact.  
Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 2 of 7

Version: 2.0

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Saponin	8047-15-2	232-462-6	Not Listed	*
Formaldehyde	50-00-0	200-001-8	C;R34 Carc. Cat.3;R40 R43 T;R23/24/25	0.1 - <1.0%
Aluminum potassium sulfate	7784-24-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Clostridium perfringens type C	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium chauvoei	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium sordellii	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium septicum	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium perfringens type D	NOT ASSIGNED	Not Listed	Not Listed	*
Clostridium novyi	NOT ASSIGNED	Not Listed	Not Listed	*
Pasteurella haemolytica	NOT ASSIGNED	Not Listed	Not Listed	*

#### Additional Information:

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
<b>Skin Contact:</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Symptoms and Effects of Exposure:</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	As for primary cause of fire.
<b>Hazardous Combustion Products:</b>	Not known
<b>Fire Fighting Procedures:</b>	Dike and collect water used to fight fire.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 3 of 7

Version: 2.0

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

<b>General Handling:</b>	Use with adequate ventilation. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing.
<b>Storage Conditions:</b>	Store under refrigeration in closed container.
<b>Storage Temperature:</b>	2-7°C

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Formaldehyde

ACGIH Ceiling Threshold Limit:	0.3 ppm
ACGIH - Sensitizer Designation	Listed
Australia STEL	2 ppm
	2.5 mg/m <sup>3</sup>
Australia TWA	1 ppm
	1.2 mg/m <sup>3</sup>
Austria OEL - MAKs	Listed
Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Finland OEL - TWA	Listed
France OEL - TWA	Listed
Germany (DFG) - MAK	0.3 ppm MAK
	0.37 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Japan - OELs - Ceilings	0.2 ppm
	0.24 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	0.75 ppm
OSHA - Specifically Regulated Chemicals	0.5 ppm-Action Level
	0.75 ppm-TWA
	2 ppm-STEL

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 4 of 7

Version: 2.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Sweden OEL - TWAs	Listed

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. Exposure monitoring may be necessary to determine requirements.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Safety glasses or goggles
<b>Skin:</b>	Wear protective clothing when working with large quantities. Wash hands and arms thoroughly after handling this material.
<b>Respiratory protection:</b>	In the event of a spill where the applicable Occupational Exposure Limit (OEL) may be exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Freeze-dried preparation	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Polymerization:** Will not occur

### 10. STABILITY AND REACTIVITY

<b>Chemical Stability:</b>	Stable
<b>Conditions to Avoid:</b>	Store at 2-7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
<b>Incompatible Materials:</b>	This material can be denatured or inactivated by a variety of organic solvents, salts or heavy metals.
<b>Hazardous Decomposition Products:</b>	None expected under normal conditions.

### 11. TOXICOLOGICAL INFORMATION

<b>General Information:</b>	The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms. The primary hazards are due to the formaldehyde content.
-----------------------------	--

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### Formaldehyde

Rat Oral LD50 800 mg/kg

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 5 of 7

Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### Formaldehyde

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

**Skin Irritation / Sensitization** This product contains formaldehyde which is considered to be a skin sensitizer.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Formaldehyde

90 Day(s) Dog Inhalation Not Specified Lungs

90 Day(s) Rat Inhalation Not Specified Lungs

90 Day(s) Monkey Inhalation Not Specified Lungs

9 Day(s) Rat Inhalation 15 ppm LOAEL Respiratory system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

Embryo / Fetal Development Mouse Oral 185 mg/kg/day Not teratogenic, Maternal toxicity

Embryo / Fetal Development Rat Inhalation 40 ppm Not Teratogenic, Maternal Toxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Formaldehyde

*In Vitro* Bacterial Mutagenicity (Ames) Bacteria Positive

*In Vitro* Chromosome Aberration Rodent Positive

*In Vitro* Sister Chromatid Exchange Rodent Positive

*In Vivo* Chromosome Aberration Not specified Positive

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Formaldehyde

2 Year(s) Rat Inhalation 6 ppm LOAEL Tumors

2 Year(s) Mouse Inhalation 15 ppm LOAEL Tumors

#### Carcinogen Status:

Contains formaldehyde: potential cancer hazard. See below

##### Formaldehyde

IARC: Group 1

NTP: Listed

OSHA: Present

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

Releases to the environment should be avoided. The environmental characteristics of this material have not been fully evaluated.

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-  
sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 6 of 7

Version: 2.0

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

**EU Symbol:** Xi  
**EU Indication of danger:** Irritant

**EU Risk Phrases:** R43 - May cause sensitization by skin contact.

**EU Safety Phrases:** S24 - Avoid contact with skin.  
S37 - Wear suitable gloves.

**OSHA Label:**  
WARNING  
May cause allergic skin reaction.

#### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A

Xi



#### Saponin

**Australia (AICS):**  
**EU EINECS/ELINCS List**

Listed  
232-462-6

## MATERIAL SAFETY DATA SHEET

Material Name: Clostridium chauvoei-septicum-novyi-  
sordellii-perfringens Types C&D-pasteurella haemolytica  
Bacterin-Toxoid  
Revision date: 07-Dec-2010

Page 7 of 7

Version: 2.0

### 15. REGULATORY INFORMATION

#### Formaldehyde

CERCLA/SARA 313 Emission reporting	0.1% de minimis concentration
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	100 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	45.4 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb TPQ
California Proposition 65	100 lb
OSHA - Specifically Regulated Chemicals	carcinogen, initial date 1/1/88 (gas)
	0.5 ppm-Action Level
	0.75 ppm-TWA
	2 ppm-STEL
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 6
	200-001-8

#### Aluminum potassium sulfate

Australia (AICS):	Listed
-------------------	--------

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R34 - Causes burns.  
R43 - May cause sensitization by skin contact.  
R40 - Limited evidence of a carcinogenic effect  
R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Product Stewardship Hazard Communications  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**